

REMARKS

The undersigned thanks Examiner Jagoe for the helpful telephonic interview summarized herein. This response has been modified from the draft sent to Examiner Jagoe prior to the interview, responsive to issues as discussed during the interview.

Claims 1 and 18 have been amended. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 103(a)

Claim 1, 4, 8-12 and 15-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kodama, et al. (WO 97/02821 A2) and Godbey, et al. (PreGrant Publication No. 2002/0187181).

Kodama et al. disclose an antifungal agent in a liquid pharmaceutical composition for topical application. Godbey et al. disclose a composition comprising a polymer and plasticizer, and disclose a polyacrylate as the polymer and copolymers of ethylene oxide and propylene oxide such as Pluronic as the plasticizer. However, Godbey et al. do not teach or suggest a composition comprising "ethyl cellulose, hydropropyl methylcellulose phthalate, or polyacrylate" as the polymer and "copolymer of ethylene oxide and propylene oxide" as the plasticizer.

On the contrary, the present invention is the composition comprising both "ethyl cellulose, hydropropyl methylcellulose phthalate, or polyacrylate" as the polymer and "copolymer of ethylene oxide and propylene oxide" as the plasticizer. By employing such structure, the present invention is capable of obtaining a coating film in a glass state which has plasticity and is very soft, and stays on the tissue after application but can be easily removed by washing with water. Further, by such coating film in glass state, drug availability is increased compared to those of general preparations (See, page 18, line 12 to page 20, line 2 of the present specification).

While Godbey, et al. disclose generally "Pluronic®" at paragraph 0026, Godbey, et al. do not teach or suggest a "a water-soluble plasticizer in a form of a solid or a paste at 20°C at 1 atm

consisting of a copolymer of oxyethylene and oxypropylene having 70 or more of polymerization degree, and containing a polyoxyethylene portion having a polymerization degree of 140 to 180 and a polyoxypropylene portion having a polymerization degree of 20 to 40" as claimed (present claim 1; claim 18 includes similar language). As discussed in the interview summary, the claim language has been reworded to more clearly point out the claimed features of the plasticizer component. The claim language is further clarified by use of closed language "consisting of".

As shown by the attached product information for BASF Pluronic®, there are more than 50 species of Pluronic® listed. One of ordinary skill in the art is provided no guidance in Godbey to choose a plasticizer with the properties recited in the claims.

Applicants exemplify "Pluronic F-68" (see Table 2) which is a tradename for a plasticizer product that is generically described by the claim language. The main structure of Pluronic F-68 is EO(oxyethylene)80-PO(oxypropylene) 27-E080. The degree of polymerization of oxyethylene is $80+80=160$, and this value is more than 140 and less than 180 (that is, $140<160<180$); the degree of polymerization of oxypropylene is 27, and this value is more than 20 and less than 40 (that is, $20<27<40$); and a degree of polymerization of the copolymer is 187 (that is, more than 70). That is, Pluronic F-68 is one of the plasticizers generically recited in claims.

Formulations containing this plasticizer are described in Table 2 as Examples 2, 3, and 4. Formulations for comparison which fall outside of the scope of the claimed invention are also described. Comparative Example 3 comprises polyethylene glycol (Macrogol 200) as the plasticizer, which is also listed in paragraph 0026 of Godbey et al. Comparative Example 4 comprises octyldodecanol as the plasticizer, that is, alcohol which is listed in paragraph 0026 of Godbey et al. Comparative Examples 2, 5 and 6 comprise SDS or TLP-4 as the plasticizer, which are generally used plasticizers.

Accordingly, Godbey merely provides a listing of conventionally used plasticizers. The term "Pluronic" itself represents more than 50 different compounds and additional species are disclosed as well.

It is well established that such disclosure does not meet the requirements for adequate written description (M.P.E.P. 2163)

A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage

the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967)

As applied to the present case, the skilled art worker could never have envisaged the use of the particular plasticizers described in Applicants' claims from the listing provided by Godbey, et al.

Furthermore, by use of the specific formulations claimed by Applicants, the formulation for application of an anti-fungal agent has advantageous properties. That is, the "the coating film being maintained on a skin or nail surface at least 12 hours from drying after application, and the coating film being removable with water" (amended claims 1 and 18). Support for the amendment is found throughout the specification. See page 19, lines 3-10; page 26, lines 2-4 and Table 3.

The characteristics of the coating films formed by compositions of Examples and Comparative Examples were examined in Example 5. The results are shown in Table 3. Comparative Examples 3 and 4 comprise plasticizers which are included in the listing of Godbey et al. According to the Table, the formulations of Comparative Examples 3 and 4 were more than half removed after 12 hours.

On the other hand, Comparative Examples 2, 5 and 6 were solid coating films, same as the coating films shown in the Examples of Godbey et al. Such solid coating films were hard and cannot be removed by washing with water. In such solid coating films, transfer ability of drug was low, as shown in Example 6 and Fig. 2 of the present application. This is because drugs are fixed in the coating films and cannot be transferred into tissues.

On the contrary, compositions of Examples 3 and 4 of the present invention formed coating films in a glass state, and showed excellent transfer ability of drug into tissues. This is because the coating films are in a glass state, and coating film preparations themselves partially transfer into tissues but not all remained on the tissues. Also, drug(s) in the preparation can move in the preparation and transfer into tissues, since drug(s) in the preparation have movement flexibility so that transfer ability of drug into tissues is increased.

As discussed above, Godbey, et al. as a whole, taken with or without Kodama, et al., do not teach Applicants' invention. Applicants particularly distinguish Examples 14-18 of Godbey, et al. from the claimed invention.

Godbey, et al. teach water-dispersible films in paragraphs 0068-0069 including Examples 14-18 of Godbey (paragraph 0069) which describes adhesive coatings laminated to strips such as a strip of plasticized polyvinyl alcohol film. Godbey teaches that these tapes could be treated with water and rubbed in and later removed by rinsing with more water. While these tapes share the property that they are removable with water, they differ in other properties and also differ structurally from Applicants' claimed compositions.

The compositions described by Godbey, et al. do not have "content of water-soluble plasticizer [which] is 1 to 10 fold with respect to the content of the film-forming agent" (Applicants' claims 1 and 18). That is, there is either the *same amount or more* plasticizer relative to the film forming agent. The compositions disclosed in paragraphs 0068-0069 of Godbey et al. have *less* plasticizer than polymeric carrier (film forming agent). For example, in Example 12, the ratio of film forming agent:plasticizer is 40: 2 (i.e., 20:1). Even in highest ratio of Example 17, the ratio is 2:1.

In other words, the content of the plasticizer is 1-10 times that of the film forming agent in the present invention (the ratio of film forming agent:plasticizer is 1:1-1:10). In Examples of the present invention, the amount of the film forming agent is 1-4g and the plasticizer (Pluronic® F-68) is 5g. The mass ratio of film forming agent:plasticizer is 1:1.25-1:5, which is clearly different from the ratio of Godbey et al.

To further distance the claimed invention from Godbey, et al., claims 1 and 18 have been amended to "the content of film-forming agent in the composition is 0.1 to 10% by weight in volume" which is less quantity of the film forming agent than taught by Godbey, et al.

Accordingly, the claimed compositions are structurally different from the compositions of Godbey, et al. As a result, the claimed compositions have different properties than the compositions of Godbey, et al.

After application, the film of Godbey et al. exists independently as a hard film. If the composition of Godbey et al. is applied on a silicon lamination and dried, it forms a hard film, which could be separated from the laminated surface. But the composition of the present

invention does not form a hard film by itself. However, when it is applied to skin or nail, it forms a film. If the composition of the present invention were applied on a silicon lamination and dried, it would remain a highly-viscous liquid, which could not be separated from the lamination.

In the present invention, by absorption of parts of the composition into skin or nail as an "anchor", a film on the skin or nail is formed in a glass state after application. Because of the water-insoluble film forming agent which is different from the teaching of Godbey, et al., the composition of the present invention composition can "anchor" onto skin or nail.

Accordingly, the present claims are clearly distinguished from the water-dispersible films of Godbey et al. For example, the film forming agent in Godbey et al. is 40%, and the ratio of plasticizer /film forming agent is 0.7 (that is, in Example 16 film forming agent (10g of PVP):plasticizer (5g of PEG 400 and 2g of Brij 56) is 1: 0.7). These values are totally outside the scope of the present claims. The composition of the present invention does not form a film upon laminating. Only on a nail or skin surface, the composition forms a glass state film.

As a result of this specific structure, the coating film of the present invention shows excellent and advantageous effect such that the coating film is in glass state, not readily removable during normal living conditions, but can be easily removed by washing with water, and has high drug transfer ability into tissues.

That is, Kodama et al. and Godbey et al. taken as a whole do not teach a formulation that includes the coating film of the present invention, which is maintained at least 12 hours from drying after application, and removable with water, and has good transfer of the antifungal medication. Further, it was not known that a coating film having such special properties could be made and drug availability could be increased by such a coating film, at the time of filing this application.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather,

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any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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The Pluronic® types are block copolymers based on ethylene oxide and propylene oxide. They can function as antifoaming agents, wetting agents, and surfactants. Pluronic® surfactant is right for his needs. The Pluronic® R types tend to generate less foam than the standard Pluronic®.

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Products

Name	Business	Product Info
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Pluronic® 17R2	Consumer & Industrial Specialties	View
Pluronic® 17R4	Consumer & Industrial Specialties	View
Pluronic® 25R2	Consumer & Industrial Specialties	View
Pluronic® 25R4	Consumer & Industrial Specialties	View
Pluronic® 31R1	Consumer & Industrial Specialties	View
Pluronic® F 108 Cast Solid Surfacta	Consumer & Industrial Specialties	View
Pluronic® F 108 NF	Consumer & Industrial Specialties	View
Pluronic® F 108 Pastille	Consumer & Industrial Specialties	View
Pluronic® F 108 Prill	Consumer & Industrial Specialties	View
Pluronic® F 108NF Prill Poloxamer 338	Consumer & Industrial Specialties	View
Pluronic® F 127	Consumer & Industrial Specialties	View
Pluronic® F 127 Prill	Consumer & Industrial Specialties	View
Pluronic® F 127 NF	Consumer & Industrial Specialties	View
Pluronic® F 127 NF 500 BHT Prill	Consumer & Industrial Specialties	View
Pluronic® F 127 NF Prill Poloxamer 407	Consumer & Industrial Specialties	View
Pluronic® F 38	Consumer & Industrial Specialties	View
Pluronic® F 38 Pastille	Consumer & Industrial Specialties	View
Pluronic® F 68	Consumer & Industrial Specialties	View
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Pluronic® F 68 LF Pastille	Consumer & Industrial Specialties	View
Pluronic® F 68 NF	Consumer & Industrial Specialties	View
Pluronic® F 68 NF Prill Poloxamer 188	Consumer & Industrial Specialties	View
Pluronic® F 68 Prill	Consumer & Industrial Specialties	View
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Pluronic® F 77 Micropastille	Consumer & Industrial Specialties	View
Pluronic® F 87	Consumer & Industrial Specialties	View
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Pluronic® F 87 NF Prill Poloxamer 237	Consumer & Industrial Specialties	View
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